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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,894	03/09/2004	Joachim Brendel	26647	2872

97464 7590 01/06/2011

Scully, Scott, Murphy & Presser, P.C.
400 Garden City Plaza, Suite 300
Garden City, NY 11530

EXAMINER	
PACKARD, BENJAMIN J	
ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
01/06/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

dknoell@ssmp.com
sanofi_docketing@ssmp.com
betty@ssmp.com

Office Action Summary	Application No.	Applicant(s)	
	10/796,894	BRENDEL ET AL.	
	Examiner	Art Unit	
	BENJAMIN PACKARD	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/12/2010 has been entered.

Applicants' arguments, filed 10/12/2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 5 and 13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Brendel et al (US 6,531,495, '495, filed Oct 30, 2000, granted 3/11/2003), in view of Smith et al (US Pregrant Pub 2002/0161018).

Applicants assert the claims are allowable where the prior art does not teach administering the two components at the now recited ranges of a weight ratio of 10,000:1 to 1:1 or 100:1 to 5:1.

Examiner disagrees. As pointed out in MPEP 2144.05 IIB, only result effective variables can be optimized. A particular parameter must first be recognized as a result effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or multiple ranges of said variable may be characterized as routine experimentation. In re Antoine, 195 USPQ 6 (CCPA 1977). While the prior art does not teach the specific range instantly claimed, the prior art does teaches the "effective" amount of the active agents in Brendel et al is based on the result effective variable of treating atrial fibrillation and atrial flutter (col 1 line 30 to col 2 line 15). Thus, the skilled artisan, when making combinations of active agents as suggested by the prior art reference, would optimize the "effective" amounts based on that the ability of the composition to treat atrial fibrillation and atrial flutter, which appears to be the same as the intended use recited by the instant claims.

Note, while a *prima facia* case of obviousness may be overcome by a showing of unexpected results, such as explained in the Office Actions mailed 06/10/2010, the instantly recited ranges are not supported by the showing of unexpected results in the instant specification. Specifically, Examiner notes the instant claims recite a range based on a ratio and not a specific dosage amount, yet the results of Table 5 suggest about 10mg/kg of the compound of example 1 alone is sufficient to provide cardioversion in goats with persistent atrial fibrillation. Further, the instant specification at pg 4 lines 21-22 recites using a Kv1.5 blocker of example 1 on its own, a cardioversion was possible in a does of, for example, 10 mg/kg. Therefore, where 10mg/kg of the Kv1.5 blocker is administered with $1/10{,}000^{th}$ or $1/100^{th}$ of the secondary

drug, such as ibutilide or dofetilide, it would not appear that an increase in cardioversion would be expected. Further, while the Kv1.5 blocker is administered without the addition of the other agents, ibutilide and dofetilide are not administered at dosages other than single points (10mg/kg and 10microgram/kg respectively). Therefore, it is unclear if these compounds alone may also provide cardioversion, given no specific dosage amount is recited in the instant claims. As such, the unexpected results are not commensurate in scope of the instant claims.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN PACKARD whose telephone number is (571)270-3440. The examiner can normally be reached on M-R 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/
Examiner, Art Unit 1612